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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,884

01/22/2004

John R. Boehringer

BCLO-100US

5451

23122 7590 02/15/2008
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

02/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,884	Applicant(s) BOEHRINGER ET AL.	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 27, 28, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 27, 34, and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's amendment received on 30 November 2007.

Corrections made to the abstract have been accepted. Corrections made to claims 2 and 6 have been accepted. Claim 28 remains withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 27 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, applicant failed to disclose a "means for retaining said shaft within said tubular body" and "means for retaining said internal member within said external member." Therefore, these new limitations are considered new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations “a tubular shape with closed circumferential ends,” which is shown in Figure 3A, and “an aperture extending longitudinally from a first end to a second end of the external member,” which is shown in 3B as element 309 (it is noted that this “aperture” does not extend from a first end to a second end, but rather extends from proximal a first end to proximal a second end). Since the applicant did not disclose the combination of the two embodiments, it is unclear as to how the ends are closed if they contain a longitudinal aperture. Since the embodiment shown in Figure 3B is a non-elected species, corrections are required to clearly identify the structure shown in Figure 3A.

Claim 4 recites the limitations “closed tubular body having closed circumferential ends,” which is shown in Figure 3A, and “an aperture extending longitudinally from a first end to a second end of said body,” which is shown in 3B as element 309 (it is noted that this “aperture” does not extend from a first end to a second end, but rather extends from proximal a first end to proximal a second end). Since the applicant did not disclose the combination of the two embodiments, it is unclear as to how the ends are closed if they contain a longitudinal aperture. Since the embodiment shown in Figure 3B is a non-elected species, corrections are required to clearly identify the structure shown in Figure 3A.

Claim 12 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what the limitation “at least one of” refers to. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 16-18, 27, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosmetto et al. (5,127,412). Cosmetto discloses a device for aiding in the closure of a wound (see entire document) comprising an external member (body 30) having spaced apart apertures (35), an internal member (shaft 40) rotatably coupled to the external member (30) having spaced apart receivers (apertures 41) in line with the apertures of the external member (body 30), a suture (15) passed through the receivers (41), means for preventing the shaft from rotating in a direction opposite the first direction (45), a means for applying a rotational force to an end of the shaft to rotate the shaft with respect to the body (12), and a means for retaining the shaft within the body (for example, see Figure 18), wherein the device is capable of being placed within a wound of a human or animal if one desires to do so.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmetto et al.

Regarding claims 8-12, Cosmetto fails to disclose a coil spring. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a coil spring as the means for preventing the shaft from rotating in an opposite direction in the device of Cosmetto as a matter of design choice, since such mechanisms are well known in the art (for example, see Westcott's patent 6,120,525; describes a coil spring for driving the winding action).

Regarding claims 13-15, Cosmetto fails to disclose a coupling for providing a vacuum. However, Applicant discloses that it is well known in the art to utilize drain tubes in open wounds (page 2). Applicant further discloses that a vacuum port is optional and that it is possible to utilize drain tubes adjacent the claimed device, in which case ports and coupling devices are not necessary (page 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Cosmetto with a coupling for a drainage tube to extract

exudates from the wound, since constructing various elements into an integral structure involves only routine skill in the art.

Response to Arguments

7. Applicant's arguments filed 30 November 2007 have been fully considered but they are not persuasive.

Applicant argues that claim 12 was amended to overcome the 35 USC § 112 rejection. However, claim 12 was not amended as argued, therefore, the 35 USC § 112 rejection stands.

With respect to claims 1-18, Applicant further argues that the claims have been amended to overcome the Cosmetto reference. However, since the amendments render the claims indefinite (see above), the 35 USC § 102 and 35 USC § 103 rejections stand.

With respect to claim 27, the applicant argues that Cosmetto fails to disclose the same structural elements as were argued for claims 1 and 4. However, claim 27 does not require the same structural elements as claims 1 and 4. Therefore, the arguments with respect to claim 27 are moot.

With respect to new claims 34 and 35, applicant makes a general statement that Cosmetto fails to disclose each of the elements claimed, but failed to pinpoint which elements are lacking. The applicant is directed review the rejection above for new claims 34 and 35.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 9-5:30 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
February 11, 2008

/ (Jackie) Tan-Uyen T. Ho/
SPE of Art Unit 3773